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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,437	07/13/2000	Christopher M. Kim	CKIM 3.0-001	3371

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EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/02/2002 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/615,437	KIM, CHRISTOPHER M.	
	Examin r	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,15-18,20-22 and 25-30* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 29-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 15-18, 20-22 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The request filed on 10/16/01 for a Continued Examination under 37 CFR 1.116 is acceptable and a RCE has been established. An action on the RCE follows.

2. Claims 1-11, 15-18, 20-22 and 25-30 are pending. Applicant is reminded that in order to cancel non-elected claims, the request to cancel non-elected claims must be filed formally.

3. Claims 1-10, 29-30 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

4. Claims 11, 15-18, 20-22 and 25-28, drawn to a method of administering bee venom to a patient are being acted upon in this Office Action.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 11, 15-18, 20-22 and 26-28 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

Claims 11, 15-18, 20-22 and 26-28 as written represent a departure from the specification and the claim as originally filed. The specification and the claims as originally filed do not provide a clear support for "0.3mg or less".

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 11, 15-18, 20-22, 25-26 and 28 rejected under 35 U.S.C. 102(b) as being anticipated by Steigerwaldt *et al.* (1966, AS on PTO 1449).

Steigerwaldt *et al* teach a method of administering bee venom to a patient suffering from a condition such as Rheumatoid arthritis comprising administering to a patient simultaneously between 0.06 mg and 1.62 mg per injection of bee venom intradermally which is about 0.01 mg and about 1.0 mg per injection and one local anesthetic such as procaine hydrochloride in an amount of 0.2%, (that is 0.2 g/100 ml or 2 mg/ml) multiply by 0.1 cc or 0.1 ml per injection which is equivalent to 0.2 mg per injection which is less than 0.3 mg per injection (See page 1047, column 1, Standardized Bee Venom, column 2 second paragraph, in particular). The Bee venom is dissolved or suspended in a liquid carrier such as an isotonic solution (See page 1047, 1047, column 1, Standardized Bee Venom, in particular). The reference solution is sufficient to provide 6 mg/ml (0.06 mg /0.1 ml *10), which is between 0.1 mg and 10.0 mg of bee venom per ml or about 5.0 mg per ml. Claim 18 is included in this rejection because the dilution of 1 mg per ml of bee venom per ml is within the purview of one of skill in the art to practice the claimed invention. The reference method of administered bee venom in an amount of 0.06 mg and 0.54 mg which is about 0.05 mg and about 0.5 mg per injection (See page 1047, column 2, dosage schedule, in particular). The reference method teaches injecting bee venom in an amount of 0.18 mg, which is about 0.1 mg per injection (See page 1047, column 2, dosage schedule, in particular). The reference method also teaches administering an anesthetic such as procaine hydrochloride in an amount of 0.2% or 0.2 mg per injection, which is about 0.1 mg to about 0.3 mg per injection (See page 1047, column 1, in particular). Claim 28 is included in this rejection because sterilized bee venom solution by filtering through a 25-micron filter adds no patentable weight since the reference standardized Bee venom preparation is for in vivo use which inherently sterilized. Thus, the reference teachings anticipate the claimed invention.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 11, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steigerwaldt *et al* (1966, AS on PTO 1449), in view of U.S. Patent 6,029,863 (Of record, Feb 2000, PTO 892) or Pharmaceutical Formulary (March 2000 edition, pages 291-292, PTO 892).

The teachings of Steigerwaldt *et al* have been discussed supra.

The claimed invention as recited in claim 27 differs from the reference only by the recitation of said local anesthetic is lidocaine.

The '863 patent teaches the use of local anesthetic such as 2 to 4% lidocaine as local anesthetic to reduce the pain and discomfort caused by the bee stings thereby "calming" the victim (See column 2, lines 6-10, column 2, line 55, in particular).

The pharmaceutical formulary teaches injectable local anesthetic such as lidocaine for injection as well as topical application (See page 291-292).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the procaine hydrochloride as taught by Steigerwaldt *et al* with the lidocaine as a local anesthetic as taught by the '863 patent or the pharmaceutical formulary. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable of success in producing the claimed invention.

One having ordinary skill in the art at the time the invention was made would have been motivated to do this because the '863 patent teaches lidocaine as local anesthetic can reduce the pain and discomfort caused by the bee stings thereby "calming" the victim (See column 2, lines 6-10, column 2, line 55, in particular). The pharmaceutical formulary teaches various forms of local anesthetic such as lidocaine which can be injectable or apply topically (See page 291-292).

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
December 31, 2001

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